

REMARKS

This application pertains to novel solid lipid particles of bioactive agents and methods for the manufacture and use thereof.

In contrast to box 4) of the Office Action Summary, Claims 1-40, 42, 44 and 45 are pending, while Claims 1-15 and 37-39 have been withdrawn from consideration as drawn to non-elected subject-matter.

The Claims under consideration are Claims 16 - 36, 40, 42, 44 and 45.

CORRECTION OF THE OFFICE ACTION SUMMARY IS RESPECTFULLY REQUESTED.

It is further respectfully requested that upon allowance of claims drawn to elected subject matter the non-elected claims be rejoined.

Claims 16, 26 and 40 have been amended to recite that the coating material E) is added to avoid recrystallization of the active substance based on the disclosure given on page 5, lines 4-11 of the originally filed application. No new matter is added.

Claims 16-36, 40, 42 and 44-45 stand rejected under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Bastelberger et al. (US 6,590,022).

The Examiner correctly states that neither the Irvin nor the Westesen et al. reference disclose the claimed coating material E) being selected from the group consisting of partially hydrolyzed polyvinyl acetates, having a degree of hydrolysis of from 72 to 99 mol% and a viscosity of from 2 to 40 mPa.s.

The Examiner turns to the Bastelberger et al. reference to find said further limitation.

Pursuant to the present invention, the selection of the aforesaid coating material E) enables an optimum between a polymeric, stable coat on the active substance and a prevention of recrystallization.

Accordingly, one of ordinary skill in the art – when departing from the combined teaching of the Irvin and Westesen et al. reference – would need to solve the problem of providing a polymeric, stable coat and a prevention of recrystallization of the “active substance”.

The Bastelberger et al. reference pertains to “a process for preparing protective-colloid-stabilized vinylaromatic-1,3-diene copolymers” (title), which are used in “mortar” (col. 1, lines 48-49) and which shall have a satisfactory “cement stability” (see col. 1, lines 50-51 and col. 2, lines 65-67).

Accordingly the Bastelberger et al. reference pertains to a field of endeavor

totally distinct from Applicants' invention. Namely, the Bastelberger et al. reference pertains to the improvement of additives to mortar (i.e. construction of concrete buildings) while Applicants' invention pertains to active substances which are "active pharmaceutical substances, active agrochemical substances, vitamins, carotenoids and aromas which are solid at room temperature (25°C)" (see page 5, lines 23-25 of the filed application).

The process in which the Bastelberger et al. reference makes use of the "partially hydrolysed polyvinyl acetates..." (see col. 6, lines 12-15 as cited by the Examiner) is a process of polymerization (see col. 4, lines 47-51). Accordingly the partially hydrolysed polyvinyl acetates in the Bastelberger et al. reference are admixed with a polymerization mixture (see also col. 3, lines 2-11) and not to a process in which (as in the presently claimed invention, as recited in Claim 16) an active substance (already finally present in an amorphous state prior to the process) is emulsified and coated.

Due to the fact that the co-polymers of the Bastelberger et al. reference are formed within the process, a stabilization, particularly against recrystallization, as presently achieved with the partially hydrolysed polyvinyl acetates is not intended therein.

It is respectfully pointed out that the disclosure cited by the Examiner in col. 1 of the Bastelberger et al. reference does not pertain to the invention of the Bastelberger et al. reference, but refers to the discussion of the prior art, which – in view of the field of

endeavor the Bastelberger et al. reference pertains to – needs to be read in view of his invention. Thus, when the Bastelberger et al. reference discloses therein that “protective-colloid-stabilized polymers (...) are used in a wide variety of applications, for example as coating compositions or adhesives” (col. 1, lines 12-15), one of ordinary skill in the art would not read this as of being applicable to “active substances”.

With regard to the citation of col. 1, lines 27-30, it is respectfully pointed out that the disclosure given there pertains to the nature of the polymer to be coated and not to the coating itself. Thus, when Bastelberger et al. disclose that “polyvinyl acetate copolymers (...) have been established”, Bastelberger et al. do not disclose that the polymer is coated therewith, but that the polymer being coated is made from said “polyvinyl acetate”.

Accordingly the Bastelberger et al. reference does not overcome the discrepancy, as it is concerned with a completely distinct field of endeavor and – even if one of ordinary skill in the art would refer to the disclosure of the Bastelberger et al. reference – would not be able to overcome the discrepancy between the combined disclosure of the Irvin and Westesen et al. reference and Applicants' invention, as there is no teaching or suggestion that the partially hydrolysed polyvinyl acetates might help to avoid recrystallization (which is not even existent in the process of the Bastelberger et al. reference).

With regard to Claims 26 and 40 and the therein recited polyvinyl alcohol, polyvinyl pyrrolidone and saccharides, the foregoing applies mutatis mutandis.

The rejection of claims 16-36, 40, 42 and 44-45 under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Bastelberger et al. (US 6,590,022) should therefore now be withdrawn.

Claims 16-36, 40, 42 and 44-45 stand rejected under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Jordan et al. (US 2002/0103285).

In contrast to the Bastelberger et al. reference referred to above, the Jordan et al. reference does pertain to the field of handling "active substances".

However, as in the Bastelberger et al. reference, the Jordan et al. reference fails to teach or suggest that the "partially hydrolysed polyvinyl acetates", or the "polyvinyl alcohol, polyvinyl pyrrolidone and saccharides" respectively are capable of avoiding recrystallization of the active substance.

Thus one of ordinary skill in the art would not be led to use these for the above mentioned purpose in the process of the combined teaching of the Irvin and Westesen et al. references.

In view of the foregoing, the rejection of claims 16-36, 40, 42 and 44-45 under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Jordan et al. (US 2002/0103285) should now be

withdrawn.

Claim 42 stands rejected under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Bastelberger et al. (US 6,590,022) OR further in view of Jordan et al. (US 2002/0103285) "as discussed before" and further in view of Rochling et al. (US 6,602,823).

The differences between Applicants' claims and anything that could be learned from the Irvin/Westesen and Bastelberger OR Jordan references have been discussed above. There is nothing to be found in the Rochling reference that could possibly overcome these differences.

The rejection of claim 42 under 35 U.S.C. 103(a) as obvious over Irvin (US 7,276,184) in view of Westesen et al. (US 5,885,486) and further in view of Bastelberger et al. (US 6,590,022) OR further in view of Jordan et al. (US 2002/0103285) "as discussed before" and further in view of Rochling et al. (US 6,602,823) should therefore now be withdrawn as well.

In view of the present amendments and remarks it is believed that claims 1-40, 42, 44 and 45 are now in condition for allowance. Reconsideration of said claims by the Examiner is respectfully requested and the allowance thereof is courteously solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this amendment is required, applicants request that this be considered a petition therefore. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,
NORRIS, McLAUGHLIN & MARCUS, P.A.

By /William C. Gerstenzang/
William C. Gerstenzang
Reg. No. 27,552

WCG/smm/tmo

875 Third Avenue, 8th Floor
New York, NY 10022
(212) 808-0700
Fax: (212) 808-0844